STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BUREAU OF PROFESSIONAL LICENSING BOARD OF PHARMACY DISCIPLINARY SUBCOMMITTEE

In the Matter of

SUPER MART PHARMACY License Nos. 53-01-009405 and 53-15-047522,

File No. 53-17-148292

Respondent.

ORDER OF SUMMARY SUSPENSION AND FOR SEIZURE OF CONTROLLED SUBSTANCES

The Department filed an *Administrative Complaint* against Respondent as provided by the Public Health Code, MCL 333.1101 *et seq.*, the rules promulgated under the Code, and the Administrative Procedures Act, MCL 24.201 *et seq.*

After careful consideration and after consultation with the Chairperson of the Board of Pharmacy pursuant to MCL 333.7314(2), the Department finds that there is an imminent danger to the public health or safety that requires emergency action.

Therefore, IT IS ORDERED that Respondent's controlled substance license is SUMMARILY SUSPENDED, commencing the date this *Order* is served.

IT IS FURTHER ORDERED that, pursuant to Article 7 of the Code, MCL 333.7101 *et seq.*, all controlled substances owned or possessed by Respondent at the time the *Administrative Complaint* was filed before the Disciplinary Subcommittee shall be seized by the Department pending completion of proceedings.

Under Mich Admin Code, R 792.10702, Respondent may petition for the dissolution of this *Order* by filing a document clearly titled **Petition for Dissolution of Summary Suspension** with the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF

LICENSING AND REGULATORY AFFAIRS

Dated: 3-13, 2018

By: Cheryl Wykoff Pezon, Acting Director

Bureau of Professional Licensing

STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BUREAU OF PROFESSIONAL LICENSING BOARD OF PHARMACY DISCIPLINARY SUBCOMMITTEE

In the Matter of

SUPER MART PHARMACY License Nos. 53-01-009405 and 53-15-047522,

File No. 53-17-148292

Respo	ndent.
-------	--------

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Cheryl Wykoff Pezon, Acting Director, Bureau of Professional Licensing, complains against Respondent Super Mart Pharmacy as follows:

- 1. The Michigan Board of Pharmacy is an administrative agency established by the Public Health Code, MCL 333.1101 *et seq.* The Board's Disciplinary Subcommittee is empowered to discipline licensees for Code violations.
- 2. The Board administers the controlled substance provisions in Article 7 of the Code, MCL 333.7101 .7545, and is empowered to discipline licensees for Article 7 violations under MCL 333.7311(1).
 - 3. MCL 333.7333(1) provides, in pertinent part:

"[G]ood faith" means the prescribing or dispensing of a controlled substance by a practitioner . . . to or for an individual Application of good faith to a pharmacist means the dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

(a) Lack of consistency in the doctor-patient relationship.

- (b) Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients.
- (c) Quantities beyond those normally prescribed for the same drug.
- (d) Unusual dosages.
- (e) Unusual geographic distances between patient, pharmacist, and prescriber.
- 4. Mich Admin Code, R 338.490(2) provides:

A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

- (a) The prescription appears to be improperly written.
- (b) The prescription is susceptible to more than 1 interpretation.
- (c) The pharmacist has reason to believe that the prescription could cause harm to the patient.
- (d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.
- 5. Respondent holds a pharmacy license no. 53-01-009405 and a controlled substance license no. 53-15-047522. After consultation with the Board Chairperson, the Department found that there is an imminent danger to the public health or safety that warrants suspension of Respondent's controlled substance license. Therefore, pursuant to MCL 333.7314(2), the Department summarily suspended Respondent's State of Michigan controlled substance license, effective on the date the accompanying *Order of Summary Suspension* was served.
 - 6. Respondent is a licensed pharmacy located in Detroit, Michigan.
- 7. Department records indicate that from August 16, 2010 until approximately January 17, 2018, Respondent's pharmacist-in-charge (PIC) was Zafar

Aziz, R.Ph.¹ Upon information and belief, Muhammad Mehmood Ashraf, R.Ph.² has been

acting as Respondent's PIC since at least September 2017.

8. Alprazolam is a benzodiazepine schedule 4 controlled substance.

Alprazolam is a commonly abused and diverted drug, particularly in its 1 mg and 2 mg

dosages.

9. Carisoprodol is a muscle relaxant and a schedule 4 controlled

substance. Carisoprodol has significant potential for abuse, dependence, overdose, and

withdrawal, particularly when used in conjunction with opioids and benzodiazepines.

10. Codeine/acetaminophen combination drugs are commonly abused

and diverted schedule 3 controlled substances.

11. Codeine preparations (e.g., codeine/promethazine syrup) are

schedule 5 controlled substances prescribed for treating cough and related upper

respiratory symptoms. Codeine/promethazine syrup is rarely indicated for any other

health condition, and is particularly ill-suited for long-term treatment of chronic pain.

Codeine/promethazine syrup is a highly sought-after drug of abuse, and is known by the

street names "lean," "purple drank," and "sizzurp."

12. Diazepam (e.g., Valium) is a benzodiazepine schedule 4 controlled

substance.

13. Hydrocodone, and combination products including hydrocodone are

commonly abused and diverted opioid schedule 2 controlled substances.

¹The Department has also filed an Administrative Complaint against Aziz for the conduct alleged

here. Zafar Aziz, R.Ph., No. 53-17-148293.

² The Department has also filed an Administrative Complaint against Ashraf for the conduct alleged here. *Muhammad Mehmood Ashraf*, *R.Ph.*, No. 53-18-149851.

14. Oxycodone (e.g., Percocet), a schedule 2 controlled substance, is an opioid used to treat pain, and is commonly abused and diverted.

15. Oxymorphone, a schedule 2 controlled substance, is an opioid used to treat pain, and is a commonly abused and diverted drug. Oxymorphone 40 mg is the most commonly abused and diverted strength of oxymorphone.

16. Lorazepam is a schedule 4 benzodiazepine controlled substance.

17. Zolpidem (e.g., Ambien), a schedule 4 controlled substance, is a non-benzodiazepine hypnotic with sedative properties used to treat sleep disorders, and is commonly abused and diverted.

18. When used in combination, opioids, muscle relaxants, and benzodiazepines can produce a feeling of euphoria. These combinations are highly desired for diversion and abuse and have the street name "Holy Trinity."

19. The Centers for Disease Control and Prevention (CDC) guidelines for opioid prescribing direct providers to avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

20. The CDC's guidelines for opioid prescribing direct providers to use "extra precautions" when prescribing opioids with a daily morphine milligram equivalent (MME) of 50 or more. Those guidelines also direct providers to "avoid or carefully justify" increasing dosage to a daily MME of 90 or more.

Respondent's Dispensing Data

21. The Department reviewed data from the Michigan Automated Prescription System (MAPS), the State of Michigan's prescription monitoring program, which gathers data regarding controlled substances prescribed and dispensed in Michigan. The Department discovered that Respondent's dispensing of oxymorphone 40 mg, oxymorphone (all strengths), and oxycodone 30 mg escalated from 2015 through 2017. The Department also found that Respondent was the among the highest-ranked dispensers of the following commonly abused and diverted controlled substances among all Michigan dispensers in the following quarters of 2016 and 2017:

Drug	2016 Q3 Rank	2016 Q4 Rank	2017 Q1 Rank	2017 Q2 Rank	2017 Q3 Rank	2017 Q4 Rank
Oxymorphone 40 mg	48	2	1	1	1	1
Oxymorphone (all strengths)	75	2	1	1	1	1
Oxycodone 30 mg	58	25	15	10	16	16

22. During the following periods, Respondent filled prescriptions for the following commonly abused and diverted controlled substances in the following quantities:

		2016	2017 (thru November 30)
(a)	Oxycodone 30 mg	519 (20.04%)	663 (26.90%)
(b)	Hydrocodone/apap 10-325 mg	396 (15.29%)	195 (7.91%)
(c)	Oxymorphone 40 mg	247 (9.54%)	775 (31.44%)
(d)	Alprazolam 2 mg	152 (5.87%)	45 (1.83%)
(e)	Total, (a) – (d)	1,314 (50.73%)	1,678 (68.07%)
(f)	Total CS prescriptions	2590	2465

23. Patients paid cash for 27.10% of the prescriptions Respondent filled between January 1, 2017 and November 30, 2017. This rate is several times the state average of approximately 10% for cash payment and suggests that prescriptions were filled for illegitimate purposes.

Inspection of Respondent's Business Premises

- 24. The Department inspected Respondent's business premises on December 19, 2017. The Department's investigator noted violations of regulations governing pharmacies, including out of date policies and procedures for delegated tasks, lack of up-to-date reference materials, and Mr. Ashraf's pharmacist license not properly posted.
- 25. The Department's investigator observed an unidentified man in the pharmacy area working at a computer and handling medications. The investigator asked Mr. Ashraf to identify the individual. Mr. Ashraf told the investigator he did not know who the man was, and failed to identify him despite repeated questioning by the investigator.

Pharmacist-In Charge

- 26. At the inspection, Mr. Ashraf provided the following information:
 - a. Mr. Ashraf has been employed as a pharmacist at Respondent since July 2016 and has been Respondent's PIC since August or September 2017. Mr. Ashraf is really the only pharmacist that works at Respondent, aside from relief pharmacists when Mr. Ashraf takes time off.
 - b. Mr. Aziz owns Respondent, does not work at the pharmacy, and is often out of the country.

27. At the inspection, the Department's investigator noted that Respondent failed to timely notify the Department it had changed its PIC from Mr. Aziz to Mr. Ashraf. Department records indicate that Respondent's PIC change did not take effect until approximately January 17, 2018.

Verifying Prescriptions

- 28. The Department learned that in August 2017, fraudulent prescriptions were being issued in prescriber "M"'s name. Prescriber "M"'s office manager compiled a list of patients and pharmacies that dispensed the medications and contacted the pharmacies about the fraudulent prescriptions. Respondent appeared on the list, with 38 patients representing 126 fraudulent prescriptions. The Department also learned that prescriber "M" had not practiced since the last week of August 2017; since August 29, 2017, Respondent dispensed 202 oxycodone prescriptions under prescriber "M."
- 29. During the December 19, 2017 inspection, the Department's investigator reviewed several recently-filled prescriptions and discovered a set of four prescriptions with fold marks in the same spot, written by prescriber "M," for the same medication (oxycodone 30 mg). Mr. Ashraf first stated that the patients all individually brought the prescriptions to Respondent to be filled, but later stated that a caregiver brought the prescriptions in for the patients. The investigator also found a second, similarly folded set of prescriptions from prescriber "M" for oxycodone 30 mg.
- 30. The Department's investigator also asked Mr. Ashraf why he was dispensing prescriptions from prescriber "R," when all of the prescriptions written by "R" were for oxymorphone 40 mg and prescriber "R" does not prescribe anything else. Mr. Ashraf said that Mr. Aziz had visited prescriber "R" and said that he was "OK."

31. When the Department's investigator asked Mr. Ashraf if he was concerned about pattern prescribing from prescribers "M" and "R," Mr. Ashraf replied that he verifies every prescription from the prescribers.

Identifying Red Flags for Abuse and Diversion

- 32. During the December 19, 2017 inspection, Mr. Ashraf provided the following information:
 - a. Mr. Ashraf reviews MAPS before dispensing controlled substances and documents this verification on the prescriptions.
 - b. Mr. Ashraf verifies controlled substance prescriptions with the prescriber and documents the verification on the prescriptions.
 - c. Mr. Ashraf was familiar with the red flags for diversion of controlled substances, and was aware oxycodone, oxymorphone, and promethazine with codeine were highly diverted and abused medications.
 - d. If a patient is receiving an opioid, Mr. Ashraf does not dispense promethazine with codeine to the patient.
 - e. Mr. Ashraf is familiar with CDC recommendations discouraging prescribing opioids and benzodiazepines concurrently and morphine equivalent dosing.
 - f. If Mr. Ashraf dispenses an opioid to a patient, he only dispenses one opioid at a time.
 - g. Mr. Ashraf was familiar with the combination of drugs known as the "Holy Trinity."
- 33. Contrary to Mr. Ashraf's statements on December 19, 2017, the Department found evidence that Respondent had dispensed promethazine with codeine to patients filling opioid prescriptions and had dispensed more than one opioid prescription to individual patients.

Patient Examples

- 34. The Department reviewed MAPS data for 10 patients to whom Respondent dispensed prescriptions to during the review period of December 7, 2015 through December 7, 2017. All of those patients repeatedly filled prescriptions for commonly abused and diverted controlled substances at Respondent during that period:
 - (a) Patient PD filled several combinations of controlled substance prescriptions on the same day over the review period. Combinations included:
 - i. An opioid and a muscle relaxant;
 - ii. An opioid and promethazine with codeine;
 - iii. An opioid, promethazine with codeine, and a hypnotic;
 - iv. An opioid, benzodiazepine, and a hypnotic;
 - v. A muscle relaxant and a hypnotic;
 - vi. A benzodiazepine and a muscle relaxant;
 - vii. A benzodiazepine and a hypnotic;
 - viii. A benzodiazepine, muscle relaxant, and a hypnotic; and
 - ix. The Holy Trinity and a hypnotic.

Patient PD filled approximately 84 controlled substance prescriptions at Respondent during the review period.

- (b) Patient DM filled prescriptions for an opioid and benzodiazepine on the same day on 11 occasions. On six of those occasions, patient DM also filled a prescription for a hypnotic. Multiple times, Patient DM filled prescriptions on the same day for a benzodiazepine and a hypnotic; several times patient DM filled this combination in close proximity to filling an opioid prescription. Overall, patient DM filled approximately 63 controlled substance prescriptions at Respondent during the review period.
- (c) Patient YM filled prescriptions for an opioid, benzodiazepine, and a hypnotic on the same day nine times during the review period. Overall, patient YM filled approximately 47 controlled substance prescriptions at Respondent during the review period.

- (d) Patient TO filled prescriptions for an opioid and a muscle relaxant on the same day on four occasions during the review period. Patient TO filled prescriptions for an opioid and promethazine with codeine on the same day on four occasions during the review period; on two of those occasions, patient TO filled a second opioid prescription. Overall, patient TO filled approximately 27 controlled substance prescriptions at Respondent during the review period.
- (e) Patient LP filled ten prescriptions for oxymorphone 40 mg at Respondent during the review period, each written by prescriber "R." Each prescription carried an MME of 240.00.
- (f) <u>Patient TP</u>'s filled prescriptions show patterns of dispensing. Patterns include:
 - i. From approximately September 30, 2016 through May 8, 2017, patient TP filled a prescription for an opioid, then filled prescriptions for promethazine with codeine and a muscle relaxant on the same day approximately 10 days later. This pattern occurred eight times. On three of those occasions, patient TP also filled a prescription for a benzodiazepine on the same day the opioid prescription was filled.
 - ii. From approximately May 26, 2017 through December 7, 2017, patient TP filled prescriptions for an opioid and a benzodiazepine on the same day, and approximately 10 days later, filled a prescription for a muscle relaxant. This pattern occurred seven times.

Patient TP also filled prescriptions for an opioid, a muscle relaxant, and promethazine with codeine either on the same day or within one day two times. Overall, patient TP filled approximately 68 controlled substance prescriptions at Respondent during the review period.

- (g) Patient SW filled prescriptions for an opioid and a benzodiazepine on the same day on 17 occasions. Overall, patient SW filled approximately 45 controlled substance prescriptions at Respondent during the review period.
- (h) <u>Patient YW</u> filled several combinations of controlled substance prescriptions on the same day over the review period. Combinations included:
 - i. An opioid and a muscle relaxant;
 - ii. An opioid and promethazine with codeine;
 - iii. An opioid and a benzodiazepine;

- iv. Promethazine with codeine and a muscle relaxant;
- v. Promethazine with codeine and a benzodiazepine;
- vi. Two benzodiazepines; and
- vii. The Holy Trinity.

Overall, patient YW filled approximately 84 controlled substance prescriptions at Respondent during the review period. Patient YW received prescriptions (filled at Respondent and other pharmacies) from 18 providers.

- Patient EW's filled prescriptions show a pattern of dispensing. Patient EW filled prescriptions for a muscle relaxant (mostly at other pharmacies, and at Respondent once) and approximately one to three weeks later, filled prescriptions for an opioid and a benzodiazepine one the same day at Respondent. This occurred sequentially 17 times. Aside from the prescriptions included in the above pattern, patient EW filled prescriptions for an opioid and a benzodiazepine on the same day at Respondent three times. Overall, patient EW filled approximately 43 controlled substance prescriptions at Respondent during the review period.
- (j) Patient JW filled 12 prescriptions for oxymorphone 40 mg at Respondent during the review period, each written by prescriber "R." Each prescription carried an MME of 240.00.

COUNT I

Respondent failed to maintain effective controls against diversion of controlled substances to other than legitimate and professionally recognized therapeutic, scientific, or industrial uses, in violation of MCL 333.7311(1)(e).

COUNT II

Respondent dispensed controlled substances for other than legitimate or professionally recognized therapeutic, scientific, or industrial purposes, or outside the Respondent's scope of practice, in violation of MCL 333.7311(1)(g).

COUNT III

Respondent dispensed controlled substances without good faith, contrary

to MCL 333.7333(1) and in violation of 333.7311(1)(h).

COUNT IV

Respondent's conduct, as described above, evidences a failure to report to

the Department a PIC change not later than 30 days after the change occurs, contrary to

MCL 333.17748(4), in violation of MCL 333.17768(1).

COUNT V

Respondent's conduct, as described above, evidences a failure to have a

PIC working an average of at least 8 hours per week at the pharmacy, contrary to MCL

333.17748(3), in violation of MCL 333.17768(1).

COUNT VI

Respondent's conduct, as described above, evidences a failure to maintain

the necessary professional and technical equipment and supplies, contrary to Mich Admin

Code, R 338.481, in violation of MCL 333.17768(1).

COUNT VII

Respondent's conduct, as described above, evidences a failure to maintain

updated policies and procedures for delegated tasks, contrary to Mich Admin Code, R

338.490(5)(c), in violation of MCL 333.17768(1).

RESPONDENT IS NOTIFIED that, consistent with Mich Admin Code, R 338.1615(3), Respondent has 30 days from the date of receipt of this complaint to answer this complaint in writing and to show compliance with all lawful requirements for retention of the license. Respondent shall submit the response to the Bureau of Professional Licensing, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF

LICENSING AND REGULATORY AFFAIRS

Dated: 3-13, 2018

By: Cheryl Wykoff Pezon, Acting Director

Bureau of Professional Licensing

S:\Drug Monitoring Section\Staff Folders\Prygoski.J\Super Mart Pharmacy\Super Mart Pharmacy AC + OSS, 148293.docx